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| APPLICATION NO.                        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/700,999                             | 12/04/2000  | Stephen M. Wiener    | 4239-56467          | 4557             |
| 36218                                  | 7590        | 04/09/2007           | EXAMINER            |                  |
| KLARQUIST SPARKMAN, LLP                |             |                      | STIGELL, THEODORE J |                  |
| 121 S.W. SALMON STREET                 |             |                      | ART UNIT            | PAPER NUMBER     |
| SUITE #1600                            |             |                      | 3763                |                  |
| PORTLAND, OR 97204-2988                |             |                      |                     |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE |             | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS                               |             | 04/09/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/700,999             | WIENER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Theodore J. Stigell    | 3763                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 December 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-51,57-66,68,69,79 and 80 is/are pending in the application.
- 4a) Of the above claim(s) 1-51 and 57-60 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 61-66,68,69,79 and 80 is/are rejected.
- 7) Claim(s) 61-66,68,69,79 and 80 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Claim Objections***

Claims 61-66, 68-69, and 79-80 are objected to because of the following informalities: It is clear from the drawings (figure 19) that the cannula and catheter are separate devices. Therefore, the claims would more accurately describe the invention if they recited an "access system" instead of an "access device". Appropriate correction is suggested.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-63, 66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierpoint (5,484,412). Pierpoint discloses an access device for targeted delivery of therapeutic or diagnostic agents comprising an elongated cannula (22) having a wall, proximal and distal ends, and a lumen configured to contain a trochar, first and second balloons (38,36) spaced axially along the cannula at positions such that, when the cannula is inserted through the wall of the desired body organ and the balloons are inflated, the first balloon can engage an inner surface of the organ and the second balloon can engage an outer surface of the organ, holding the distal end of the cannula in position within the hollow space inside the organ and substantially sealing

against leaks, and a flexible balloon catheter (18) having an exterior and a distal tip, the catheter being capable of insertion through the cannula, the catheter including an inflatable balloon (18a) near its distal tip, that upon inflation is capable of occluding a duct communicating with the organ, further comprising a drainage line (lumen of 22), inflation ports at the proximal end of the cannula, wherein the cannula is made of bio-compatible materials and the catheter comprises multiple lumens (20,20B).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierpoint (5,484,412) in view of Parks et al. (5,250,040). Pierpoint discloses all of the limitations as recited in claim 61, but fails to disclose an occluder comprising a cannula cap. Parks discloses a cap (40) to occlude the lumen of the cannula when not in use to reduce the risk of infection. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the cannula of Pierpoint with the modifications as disclosed by Parks to make an access device that could reduce the risk of internal infection.

Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierpoint (5,484,412) in view of Antoshkiw et al. (4,024,873). Pierpoint discloses all of the limitations as recited in claim 61, but fails to disclose a pressure transducer at the distal end of the catheter. Antoshkiw discloses a pressure transducer at the distal end of the catheter that is used to measure the pressure of the lumen the catheter is being inserted into. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the catheter of Pierpoint with the modifications as disclosed by Antoshkiw to make an access device that could measure the internal pressure of the body.

***Response to Arguments***

Applicant's arguments with respect to claims 61-66, 68-69, and 79-80 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
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